IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No.: 2928
JOHANNES MEERDINK NILS DAN ANDERS SÖDERGARD	Group Art Unit: 1625
Serial No.: 10/582,280	Examiner: Raymond K. Covington
Filed: June 9, 2006	Attorney Docket: 2144.000800/RFE (PN756131US)
For: PURIFICATION PROCESS FOR LACTIDE	**CUSTOMER NO. 23720**

Noted
12/08/2010
/RC/

REPLY BRIEF

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby submit a Reply Brief. No fee should be required for filing this Reply Brief. If any fee is required, the Director is authorized to deduct the fee from Williams, Morgan & Amerson, P.C. Deposit Account No. 50-0786/2144.000800RE.

I. The Appeal Brief Contains All Information Required by 37 C.F.R. § 1.192(c)

Applicants agree with the Examiner's statements regarding the real party in interest and related appeals, interferences, or judicial proceedings at sections 1 and 2 of the Examiner's Answer dated August 3, 2010 ("the Answer"). Applicants acknowledge that the Examiner has found the statements regarding the status of claims, the status of amendments after final rejection, the summary of claimed subject matter, the grounds of rejection to be reviewed on appeal, and the claims appendix at sections 3, 4, 5, 6, and 7 of the Answer to be correct.

II. Applicants' Reply to Examiner's Statement of Grounds of Rejection

A. Rejection of claims 1-21 under 35 U.S.C. § 103(a)

In the Answer, the Examiner maintained his rejection of claims 1-21 as allegedly being unpatentable under 35 U.S.C. § 103(a) over O'Brien, et al., US 5,521,278 ("O'Brien") and Drysdale, et al., US 5,236,560 ("Drysdale"). Appellants submit his position is incorrect, for at least the reasons set forth below.

As a reminder, claim 1, and claims 2-21 dependent thereon (i.e., all pending claims) are directed to a process for the purification of lactide from a crude lactide vapour product stream comprising at least said lactide, lactic acid, water and linear lactic acid oligomers, said crude lactide vapour product stream being produced by depolymerisation of low molecular weight polylactic acid in a reactor. Among other steps, the process comprises:

feeding said vapour product stream to a rectification column having a feed inlet at the lower end of the column and an overhead vapour outlet at the upper end of the column, through the said feed inlet, said column being mounted onto the reactor such that components from the vapour product stream liquefying within the column are allowed to flow back into the reactor.

The person of ordinary skill in the art would understand that the components liquefying in the rectification column, and allowed to flow back into the reactor, are unreacted oligomers, which may be referred to as "heavy ends." The person of ordinary skill in the art would understand that whatever further processing might be done to lactide and vapor in the product stream is *irrelevant* for consideration of what to do with the unreacted oligomers, a.k.a. heavy ends.

Appellants have repeatedly pointed out that O'Brien or Drysdale, alone or in combination, *fail* to teach or suggest a rectification column, let alone one mounted on the reactor as recited. Further, O'Brien or Drysdale, alone or in combination, *fail* to teach or suggest liquefying unreacted oligomers and allowing them to flow back into a reactor, as recited.

The Examiner has repeatedly argued that O'Brien and Drysdale allegedly teach the functional equivalent of a rectification column mounted on a depolymerization reactor such that components from the vapour product stream liquefying within the column are allowed to flow back into the reactor. For example, at p. 4 of the Answer, the Examiner argued that O'Brien at col. 2, step E teaches removal of water and lactide as vapor. However, regardless whether the cited passage of O'Brien teaches removal of water and lactide as vapor is irrelevant for the consideration of what to do with O'Brien's heavy ends. The cited passage of O'Brien only teaches that "heavy ends are removed as molten liquid." Col. 2, line 62. This is *not* a teaching of a rectification column mounted on a depolymerization reactor such that components from the vapour product stream liquefying within the column are allowed to flow back into the reactor. Further, this is *not* a teaching that unreacted oligomers are allowed to flow back into the reactor.

For further illumination of this point, see O'Brien, col. 10, line 55 to col. 12, line 33, with reference to Figures 1a-1b. O'Brien plainly teaches that the vapor overhead of its cracking vessel

(depolymerization reactor) 900 is "removed… through line 25" and "fed through line 25 to condensor 1000." (col. 11, lines 64-66; col. 12, lines 26-30). As shown in Figures 1a-1b, condensor 1000 is *not* mounted on cracking vessel 900. The arrangement of cracking vessel 900, line 25, and condensor 1000 does *not* allow components from the vapor overhead condensing within the condensor, such as unreacted oligomers, to flow back into the cracking vessel.

O'Brien also *fails* to suggest a rectification column as presently claimed, as indicated both by the passages cited above and by O'Brien's later discussion at col. 8, line 60 to col. 9, line 18. The later passage from O'Brien teaches a two-stage process of condensing a cracker overhead (in condensor 1000) and then fractionally distilling the condensate (in distillation column 1400), with condensed material from the condensor 1000 being led through line 43 to the distillation column 1400. Unreacted oligomers, a.k.a., heavy ends, from the fractional distillation "can be recycled to the lactide vacuum distillation column or they can be recycled to one of the dehydration stages." Col. 9, lines 16-18. The recycling of heavy ends is further discussed at col. 12, lines 26-67, with reference to Figure 1b. Heavy ends from the fractional distillation are recycled by lines 57, 58, 60, or 62 to hydrolysis and/or dehydrator units 200, 500, 600, which are units upstream of the cracking vessel 900. Fig. 1a. The heavy ends are *not* recycled to the cracking vessel 900 itself. Therefore, O'Brien *fails* to teach or suggest allowing condensed heavy ends to flow back to the cracking vessel.

The Examiner also argued O'Brien's Step C (col. 3, lines 18-23) and step (c) of the present claims correspond. Answer, p. 4. As Appellants have previously pointed out, the Examiner's argument is an improper application of 35 U.S.C. § 103(a) against the present claims for at least two reasons. First, the Examiner selected steps from two different aspects of O'Brien's teachings. O'Brien's first aspect is discussed at col. 2, lines 25-67, and includes step E

discussed above. O'Brien's second aspect is discussed at col. 3, lines 1-30, and includes the step C referred to in this paragraph. The Examiner's picking and choosing from the two different aspects of O'Brien, without any recognition of differences between the aspects that would complicate any actual combination of elements of the two aspects hypothetically contemplated by the person of ordinary skill in the art, indicates a failure to establish a *prima facie* case of obviousness.

Second, the Examiner applied step E of O'Brien's first aspect as the alleged equivalent of liquefaction within the rectification column of the present claims, e.g., step (a) of claim 1, and step C of O'Brien's second aspect as the alleged equivalent of condensing a vapor fraction, e.g., step (c) of claim 1. However, step E of O'Brien's first aspect and step C of O'Brien's second aspect *teach the same thing*. To make this point clear, Appellants present the two steps side-by-side:

O'Brien, Step E, first aspect, col. 2, lines 58-62	O'Brien, Step C, second aspect, col. 3, lines 17-23
Condensing the vaporous reaction mixture and fractionating the condensate therefrom whereby lactic acid, water and minor amounts of lactide are removed as vapor overhead, concentrated lactide is removed as a liquid side stream and the heavy ends are removed as molten liquid	Condensing the vaporous reaction mixture and fractionating the condensate therefrom whereby lactic acid, water and minor amounts of lactide are removed as vapor overhead, concentrated lactide is removed as a liquid side stream and the condensate heavy ends are removed as molten liquid

It is therefore plain that the Examiner is attempting to argue one teaching of O'Brien--that of condensing a vaporous reaction mixture and fractionating the resulting condensate--is the equivalent of two different steps of the present invention (e.g., steps (a) and (c) of claim 1), which are performed on different streams in different vessels, yielding different products which are further handled in different ways.

In addition, the teachings of O'Brien discussed above relate to the processing of a lactide and water vapor stream. The teachings of O'Brien *fail* to teach or suggest allowing unreacted oligomers to flow back into a reactor, let alone by use of a rectification column mounted on the reactor, as presently recited.

The Examiner also argued that recycling reaction components is "an obvious expedient well-known to a person of ordinary skill in the distillation chemical arts." Answer, pp. 4-5. As Appellants have previously pointed out, this argument is flawed.

First, the Office recently summarized its guidelines for determining obviousness in the "2010 KSR Guidelines Update," Fed. Reg., Vol. 75, No. 169, pp. 53643-53660 ("2010 KSR Guidelines Update"). These guidelines are effective as of September 1, 2010.

Upon resolution of the *Graham* factual inquiries, reasoning is then required to support an obviousness determination. In light of *KSR*, the Office identified at least seven rationales as examples of appropriate lines of reasoning. To summarize from 2010 KSR Guidelines Update, p. 53644, col. 3:

0. The teaching-suggestion-motivation (TSM) test;

1. Combining prior art elements according to known methods to yield predictable results;

2. Simple substitution of one known element for another to obtain predictable results;

3. Use of a known technique to improve similar devices, methods, or products in the same way;

4. Applying a known technique to a known device, method, or product ready for improvement to yield predictable results;

5. Obvious to try—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and

6. Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art.

Regardless of the rationale(s) used, any rationale employed must provide a link between the factual findings and the legal conclusion of obviousness.

Whether or not recycling reaction components is "an obvious expedient well-known to a person of ordinary skill in the distillation chemical arts," under any rationale set forth above, recycling reaction components as taught by references *fails* to lead the person of ordinary skill in the art to use of a rectification column allowing components liquefying therein to flow back to a depolymerization reactor. Both O'Brien and Drysdale teach the use of multiple condensors, distillers, and lines therebetween for processing lactide vapor streams. The presently recited rectification column allowing components to flow back to the depolymerization reactor is not a known element or technique (it is not taught by O'Brien or Drysdale), so Rationales 1-4 and 6 cannot apply. O'Brien and Drysdale offer no teaching, suggestion, or motivation to modify their teachings to arrive at the present claims, so Rationale 0 cannot apply either.

The only remaining possibility would be an "obvious to try" rationale. It must be borne in mind that this rationale is only appropriate when there are a finite number of identified,

predictable solutions, and one of ordinary skill in the art could have pursued such known potential solutions with a reasonable expectation of success. At least one of the facts of the present application renders this rationale inappropriate. Use of a rectification column allowing components liquefying therein to flow back to a depolymerization reactor is unidentified by O'Brien and Drysdale. In *Rolls-Royce, PLC v. United Technologies Corp.*, 603 F.3d 1325 (Fed. Cir. 2010), the Federal Circuit pointed out that there had been no suggestion in the prior art that would have suggested Rolls-Royce's solution would have addressed the problem in that case. The same holds true here regarding O'Brien and Drysdale, which give no suggestion that use of a rectification column allowing components liquefying therein to flow back to a depolymerization reactor would be effective in recycling components. As such, Appellants' solution "would not have presented itself as an option at all, let alone an option that would have been obvious to try." *Rolls-Royce*, 603 F.3d at 1339. Because the presently claimed solution would not have been selected from a finite number of potential solutions, the obvious to try rationale cannot be used to support a conclusion of obviousness.

In addition, conclusory statements regarding common knowledge and common sense are insufficient to support a finding of obviousness. Appeals to common knowledge require explanation "with sufficient reasoning." *Perfect Web Technologies, Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, at 1328. Even if the person of ordinary skill in the art would be motivated to recycle reaction components, no reasoning has been provided as to why he or she would allegedly chose use of a rectification column allowing components liquefying therein to flow back to a depolymerization reactor, as presently claimed. From O'Brien and Drysdale, he or she would consider that multiple condensors, distillers, and lines therebetween would be required.

The Examiner made a number of factual errors regarding O'Brien and Drysdale. For example, the Examiner argued that rectification of lactide vapor would occur in the upper portion of the reaction chamber of O'Brien. Col. 7, lines 31-45. This argument fails for at least the following reasons.

It seems that the Examiner is equating the top of cracking vessel 900 of O'Brien with the rectification column according to the claimed invention, and the bottom of cracking vessel 900 of O'Brien with the reactor according to the claimed invention. However, this analysis is erroneous. The cited passage of O'Brien teaches that oligomer is fed *via* line 21 to the *top* of cracking vessel 900, which would equate in the present invention to feeding the low molecular weight polylactic acid into the rectification column rather than, as claimed, the reactor.

Then, according to O'Brien, oligomer reacts as it descends through the trays of the cracking vessel 900. Lactide vapor produced by the reaction is carried upward with the assistance of nitrogen to an outlet 25 at the top of the reactor. Unreacted heavy oligomers, *i.e.*, unreacted oligomers or heavy ends, flow downward from the lowest tray and are collected and removed from the bottom of the column. The unreacted heavy oligomers are then removed via line 29 or recycled via line 27 to a hydrolysis unit 500 and/or a dehydrator 200, 600. Col. 12, lines 17-20.

Because the unreacted heavy ends accumulate at the bottom of the reactor, it is physically impossible for them to "flow back into the reactor." Further, O'Brien explicitly teaches that the unreacted heavy ends are sent to a hydrolysis unit or a dehydrator, *not* to the reactor.

In addition, the present claims recite, among other elements, a rectification column having a feed inlet and being mounted on a depolymerization reactor. The upper portion of the reaction chamber of O'Brien cannot be mounted on the reaction chamber of which it is a portion,

and also lacks a feed inlet for lactide vapor. Therefore, the upper portion of the reaction chamber of O'Brien is *not* a rectification column.

The Examiner also cited col. 8, lines 5-8 of O'Brien. To quote, this passage states: "Sieve plate distillation trays, each bearing a liquid layer of unconverted oligomer, have been found to be very effective to mix the feed, vapor and liquid intimately and thus to improve reaction efficiency." This passage refers to a feature of O'Brien's reaction vessel, *not* a rectification column having a feed inlet and being mounted on a depolymerization vessel as presently claimed.

Turning now to Drysdale, this reference is even less relevant regarding how unreacted oligomers, a.k.a., heavy ends, from a depolymerization process should be handled. Drysdale is directed solely to downstream processing of lactide vapor. Drysdale makes no discussion of a depolymerization reactor, let alone one usable in a method as presently claimed.

The Examiner pointed to the discussion of Drysdale's Figure 2 as teaching an integrated distillation system comprising columns and condensers along with a recycle loop, which he alleges reads on the claimed rectification step. However, Drysdale's Figure 2, considered either alone or in combination with Figure 1, in light of col. 5, line 67 to col. 6, line 57, teaches *nothing* resembling the claimed rectification step and suggests a far more complex process is necessary. Specifically, Drysdale teaches taking a vapor product stream from a depolymerization unit, feeding it through line 2 to distillation column 1, removing a higher boiling bottoms stream from the distillation column 1 through line 6, feeding the stream from line 6 via line 15 to a flash still 16, removing high-boiling oligomeric residue from the flash still 16 through line 20, hydrolyzing the oligomeric residue, concentrating the hydrolysate, and feeding the concentrated hydrolysate to an oligomerization reactor for conversion to a depolymerizable lactic acid oligomer.

As should be apparent, Drysdale's discussion summarized above *fails* to teach or suggest feeding a vapor product stream to a rectification column having a feed inlet at the lower end of the column and an overhead vapor outlet at the upper end of the column, through the feed inlet, the column being mounted onto the reactor such that components from the vapor product stream liquefying within the column are allowed to flow back into the reactor.

The Examiner alleged Drysdale supports his contention at col. 3, lines 16-22. This passage of Drysdale is merely the brief description of Figure 2. At least for the reasons discussed above, "an integrated fractional distillation system comprising the columns and condensers of Fig. 1 in conjunction with… means for recycling the various vapor and liquid streams along the process loop" neither teaches nor suggests the presently claimed rectification.

The Examiner additionally alleged Drysdale supports his contention at col. 3, line 63 to col. 4, line 61. However, Drysdale here merely states the vapor product stream from a depolymerization reactor can be processed by a partial condensation step to remove water, comprising forming a condensate containing dimeric cyclic ester; recovering the condensate from the partial condensation zone; and fractionally distilling the condensate. Col. 4, line 45 to col. 5, line 3. The process disclosed here by Drysdale *fails* to teach or suggest feeding a vapor product stream to a rectification column as presently claimed.

The Examiner also alleged Drysdale supports his contention at col. 6, lines 34-50. This passage has been referred to above with regard to the discussion of Figures 1-2 and col. 5, line 67 to col. 6, line 57. The passage teaches feeding the stream from line 6 via line 15 to a flash still 16. This step, considered alone or in combination with the process disclosed by Drysdale, neither teaches nor suggests feeding a vapor product stream to a rectification column as presently claimed.

The Examiner also argued that the references teach the claimed purification can multiply occur within and without the reaction chamber. As discussed above regarding the upper portion of O'Brien's reaction chamber, the references *fail* to teach or suggest feeding a vapor product stream to a rectification column as presently claimed.

To summarize, using a rectification column mounted onto the reactor such that components from the vapor product stream liquefying within the column are allowed to flow back into the reactor is an element of the present claims undisclosed by either O'Brien or Drysdale, and one that these references fail to guide the person of ordinary skill in the art to use, let alone with any reasonable expectation of success. Therefore, claims 1-21 are patentable over O'Brien and Drysdale.

Appellants wish to point out that at several points, the Examiner used the language "it is noted" or variations thereof. If the Examiner and/or the Board are minded to consider such language as a taking of official notice, Appellants point out that neither a prior art reference nor an Examiner's affidavit (37 CFR 1.107(b)) has been cited to support this taking of "notice." *See, e.g., In re Ahlert*, 424 F.2d 1088, 1096, 165 U.S.P.Q. 418, 420 (C.C.P.A. 1970) (assertions of technical facts in areas of esoteric technology must always be supported by citation of some reference work).

Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of *instant and unquestionable demonstration as being well-known*. MPEP 2144.03. As noted by the court in *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be "capable of such instant and unquestionable demonstration as to defy dispute" (citing *In re Knapp Monarch Co.*,

296 F.2d 230, 132 USPQ 6 (CCPA 1961)). As should be apparent from Appellants' discussion of the references and the Examiner's arguments, the Examiner has presented no facts beyond the record which are capable of such instant and unquestionable demonstration as to defy dispute.

Appellants have discussed a number of factual errors and/or legal errors in this Reply Brief. Appellants have not necessarily discussed every factual error and/or legal error. Regardless, Appellants submit, in view of the foregoing discussion, claims 1-21 are patentable under 35 U.S.C. § 103(a) over O'Brien and Drysdale.

III. Conclusion

Appellants submit that all pending rejections should be overruled and claims 1-21 should be allowed.

Respectfully submitted,

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